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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/194,025	02/12/99	BOUQUET	J XI/P6155US0

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HM22/1028

EXAMINER

ZEMAN, R

ART UNIT

PAPER NUMBER

1643

DATE MAILED:

10/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/194,025

Applicant(s)
Bouquet et al.

Examiner
Robert A Zeman

Group Art Unit
1643



☒ Responsive to communication(s) filed on Feb 12, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-13 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-13 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The brief description of the Drawings on page 6 should be labeled as such. Additionally, there is no differentiation between the "LTR" and the "Deleted LTR" in the description of the drawings. It is suggested that the designation "LTR" on line 5 be amended to δ LTR to correspond to the terminology used in Figure 1.

Claim Objections

Claims 1-12 are objected to for the following informalities:

Claims 1-12 are objected to as each claim should be introduced by an article. Independent claims should be introduced by "A" or "An" and dependent claims by "The".

Claims 2, 3 and 6-12 contain the phrase "characterized in that" which is not in accordance with U.S. Patent Office practice. The use of the word "wherein" is suggested.

Claim 4 has an improper period (See page 13 line 17). The removal of the period is suggested. Additionally the use of brackets is improper since brackets are used to denote text that is to be deleted.

Appropriate corrections are required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that cell lines TDF-2A bcl-2, TCF-4.10 and TCF-4.10 bcl-2 are required in order to practice the claimed invention. Specifically, it is noted that claim 4 recites deposited material in the body of the claim and that claims 5-13 depend from claims reciting the deposited material. The deposit of biological organisms is considered by the Examiner to be necessary for enablement of the current invention {see 37 CFR 1.808(a)}. The Examiner acknowledges the deposit of organisms under Pasteur Institute National Collection of Microorganism Cultures (CNCM) accession numbers I-1709, I-1710 and I-1711, respectively, in partial compliance with this requirement. However, the deposits are not in full compliance with 37 CFR 1.803-1.809.

If a deposit is made under terms of the Budapest Treaty, then an affidavit or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty *and* that all restrictions imposed by

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the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, than an affidavit or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, should be submitted stating that the deposit has been made at an acceptable depository *and that* the following criteria have been met:

- 1) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;
- 2) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;
- 3) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- 4) a viability statement in accordance with the provisions of 37 CFR 1.807; and
- 5) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "resistant to apoptosis" in claims 1-3 is a relative term which renders the claim indefinite. The term "resistant to apoptosis" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would

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not be reasonably apprised of the scope of the invention as to how “resistant to apoptosis” a cell must be in order to fall within the scope of the claims.

Claims 3 and 5 are rejected as being indefinite. It is unclear what is meant by the phrase “derived from”. What does the applicant intend to claim with this language? The term is not sufficiently defined in the specification.

Claims 4-13 are rejected as they recite improper Markush language, rendering the claim indefinite. Proper language for claim 4 would be “.....from the group consisting of: cell line TDF-2A bcl-2, which is deposited in the CNCM (Pasteur Institute National Collection of Microorganism Cultures) under reference number I-1709; cell line TCF-4.10, which is deposited in the CNCM under the reference number I-1710; **and** cell line TCF-4.10 bcl2, which is deposited in the CNCM under reference number I-1711.

Claim 6 is rejected as being indefinite. It is unclear as to what applicant is claiming in the phrase “...they contain at least one expression cassette which comprises at least one nucleotide sequence...”. No particular expression systems are set forth such that one would be apprised of the scope of the claim. Additionally, the phrase “molecule of industrial relevance” is ambiguous and nondescriptive. It is entirely unclear what applicant intends the scope of the claim to encompass.

Regarding claim 7, the phrase “such as” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Additionally, it is unclear what is meant by “glycoprotein type”. There are many

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glycoprotein types and it is totally unclear what applicant intends the scope of the claim to be. Finally, it is unclear what is being claimed to be encoded by the nucleotide sequence, since no particular sequences are set forth.

Claims 8 and 9 do not clearly set forth the metes and bounds of the patent protection desired. Claims 8 and 9 recite the term "preferably" which fails to clearly define the invention. It is unclear whether the feature introduced by such language is the limit of the coverage desired by Applicant.

The term "able to" in claims 8 and 10 is an ambiguous term which renders the claim indefinite. Possessing the ability to do something does not mean that it actually does it. The claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim 8 is rejected as being indefinite. The claim does not clearly set forth the metes and bounds of the patent protection desired. The term "chronically" is ambiguous. Is virus being continuously produced? Sporadically produced? Is there proviral integration?

The term "integrate" in claims 10-12 renders the claim indefinite. The term "integrate" is not defined by the claim and the specification does not define the term. It is unclear whether the cells are the site of integration or merely facilitate integration elsewhere.

Claim 10 is rejected as being indefinite. It is unclear what is meant by "overexpress one or more of the genes involved in controlling the cell cycle in order to increase the rate of proliferation". It is unclear what specific genes are intended nor is it clear what the term

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“proliferation” refers to. It is unclear whether the claim is referring to the proliferation of the gene population or the cell population.

Claim 11 is rejected as being indefinite. It is unclear what is meant by “genes which encode for viral receptors”. Is the claim referring to cellular receptors utilized by viruses or receptors on the virus itself?

The term "accelerate cell growth" in claim 12 renders the claim indefinite. It is unclear what is meant by “accelerated cell growth”. What is the standard of measure? How is it measured? The claim does not clearly set forth the metes and bounds of the patent protection desired

Claim 13 is rejected as being indefinite. It is unclear what is meant by “molecules of industrial relevance”. It is entirely unclear what applicant intends the scope of the claim to encompass. Additionally claim 13 recites a method. Said method is incomplete as it refers to a single step and does not set forth positive active steps by which the method is to be performed. Finally, claim 13, apparently, recites claim 5 as a process step. Claim 5 recites immortal avian cells, not a method for culturing cells.

Claims 1-12 recite avian cells. Claim 13 recites a method for production.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 21,22 and 28-39 of copending Application No. 09/194020. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of claims 1-13 of this application is fully encompassed in those of copending Application No. 09/194020. ~~More specifically,~~

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-13 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 09/194020 which has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute

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prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future patenting of the conflicting application. The subject matter of claims 1-13 is fully encompassed in claims 1, 21, 22 and 28-39 of copending Application No. 09/194020.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bouquet et al Application No. 09/194020. Subject matter of claims 1-13 is fully encompassed in that of Application No. 09/194020.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Guilhot et al., (Oncogene 1993, Vol 8 pages 619-624) cited by Applicant on PTO 1449. Guilhot et al. discloses the immortalization of avian cells which are not transformed. See page 623 lines 4-8.

Conclusion

No claim is allowed. Claim 4 would be allowable upon satisfaction of the requirements for biological deposit and resolution of the double patenting issues.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032.


DONNA WORTMAN
PRIMARY EXAMINER

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October 27, 1999